SEP 22 2000

K002654

Special 510(k) Summary - Device Modification
Summary of Safety and Effectiveness for the Howmedica Osteonics Shoulder Screw

Proprietary Name:	Howmedica Osteonics Shoulder Screw
Common Name:	Bone Screw
Classification Name and Reference:	Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030
Proposed Regulatory Class:	Class II
Device Product Code:	OR (87) HWC
For Information contact:	Jennifer A. Daudelin, Regulatory Affairs Howmedica Osteonics Corp. 359 Veterans Boulevard Rutherford, NJ 07070-2584 (201) 507-7283 Fax: (201) 507-6870 Email: jdaudelin@howost.com

This Special 510(k) submission is intended to address a material modification to the Howmedica Osteonics Shoulder Screw. The design, manufacturing methods, intended use, packaging and sterilization of the subject device are identical to those of predicate device. The predicate screw is a preamendments device, is legally marketed, and has not been the subject of premarket notification clearance. The predicate Howmedica Osteonics Shoulder Screw is a one-quarter inch diameter, partially threaded screw available in a variety of lengths. The material modification involves adding an alternate material for this device. The predicate device is currently fabricated from cast Vitallium® (CoCr) Alloy which complies with ASTM standard F75. The subject device will be fabricated from the above referenced material and an alternate material of warm worked Vitallium® (CoCr) Alloy that conforms to ASTM F1537.

The intended use of the modified device, as described in its labeling, has not changed as a result of this modification. These devices are intended for use in cases of acromioclavicular reduction and acromioclavicular fixation; acromioclavicular reduction, coracoclavicular ligament repair, and coracoclavicular fixation; a combination of the aforementioned indications; distal clavicle excision; and muscle transfers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 2000

Ms. Jennifer A. Daudelin
Howmedica Osteonics Corporation
359 Veterans Boulevard
Rutherford, New Jersey 07070

Re: K002654
Trade Name: Howmedica Osteonics Shoulder Screw
Regulatory Class: II
Product Code: HWC
Dated: August 24, 2000
Received: August 25, 2000

Dear Ms. Daudelin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Howmedica Osteonics Shoulder Screw

Indications for Use:

The Howmedica Osteonics Shoulder Screw is intended for use in cases of acromioclavicular reduction and acromioclavicular fixation; acromioclavicular reduction, coracoclavicular ligament repair, and coracoclavicular fixation; a combination of the aforementioned indications; distal clavicle excision; and muscle transfers.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Donna R. Bochner.
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002654